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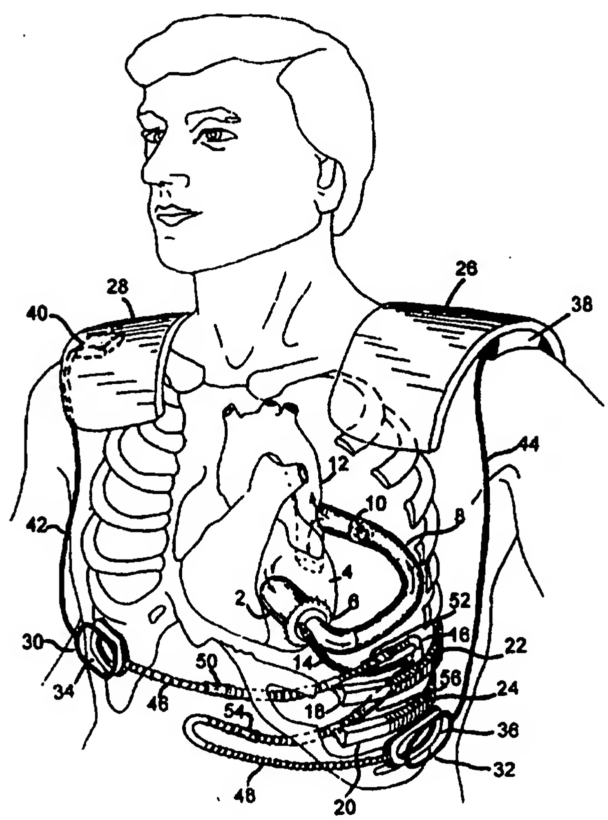
(57) Abstract

A high reliability cardiac assist system is provided for permanent use. An electric motor having dual sets of coils rotates the impeller of an intraventricular axial flow pump (2) in the preferred embodiment. The dual motor coils are powered by separate redundant battery and electronics systems (18, 20) configured such that if any wire breaks or if any electrical system component fails the pump will continue to run and sustain the life of the patient powered by the other electronics and battery system. High reliability pump bearings, pump structure to prevent failure due to thrombus, high reliability power cable conduits (46, 48) and connectors, high reliability redundant transcutaneous power transmission systems, and other sub-systems are provided which interact together in an integrated fashion to permit function for more than a decade following surgical implantation of the system without re-operation.



HIGH RELIABILITY CARDIAC ASSIST SYSTEM

BACKGROUND

Long term intraventricular cardiac assist devices are blood pumps that are surgically implanted within the diseased natural heart to support its function for extended periods of time. They must be miniaturized and must be extremely reliable. Blood pumps capable of this are disclosed in my U.S. Patents No's. 4,994,078 and 5,092,879 entitled "Intraventricular Artificial Hearts and Methods of their Surgical Implantation and Use". Four-month animal survival with these devices is reported by Macris, et al., in the American Society of Artificial Organs Proceedings for 1994. Bearing durability in excess of twenty billion revolutions has been achieved in bench tests which represents about five years of pumping at 9,000 RPM. Wear measurements of bearings after five months' implantation in a calf indicate virtually no wear with projected bearing life in excess of 20 years. These findings prove that the intraventricular approach is likely to succeed.

OBJECTS OF THE INVENTION

The object of the present invention is to provide a complete cardiac assist system including not only the blood pump and motor controller, but also all of the ancillary components that are required to provide the patient with full mobility and a high quality of life. In Table 1 of U.S. Patent No. 4,994,078 I identified transcutaneous intraventricular electric circulatory support systems as the best overall among numerous types of configurations based on availability, hemodynamic function, thrombus risk, system reliability, infection/rejection, quality of life, and cost. The object of the present invention is to provide exactly such a complete system.

Further objects of the present invention are:

1. To provide backup and redundant components which improve system safety and reliability including;

a. Dual motor windings with dual sets of motor power wires such that if any wire breaks the pump will continue to run,

b. Dual motor control electronics adapted to maintain operation of the pump in the event of failure of any electronics component,

c. Dual battery power systems adapted to maintain power to the pump in the event of failure of either one,

d. Dual sets of transcutaneous power transmission transmitter and receiver coils, permitting continued operation in the event of failure of either, and also permitting only one set to be used at a time to intermittently relieve pressure on the skin and thereby avoid tissue damage,

e. A backup valve in the outflow graft such that if the pump stops for any reason the valve will prevent aortic regurgitation and permit the residual function of the natural heart to sustain the life of the patient while the device can be repaired or replaced,

f. Implantable power cable connectors permitting replacement of components in the event of failure or when the components are worn out (such as implanted batteries), without requiring replacement of the entire system,

2. To provide thin curved battery packs worn by the patient in a "shoulder pad" configuration,

3. To provide thin curved internal battery packs implanted in the patient in place of removed ribs,

4. To provide flexible power cable conduits interconnecting the implanted components which utilize metal bellows to permit complete hermetic sealing of the pump motor and electronics,

5. To provide a control system which intermittently reduces the motor speed enough to reduce pump outflow pressure below aortic pressure, thereby causing the prosthetic valve to close and thereby helping to prevent valve thrombus,

6. To provide a control system utilizing sensors to recognize whether the patient is upright or recumbent and to adjust the pump flow according to this and other information about the patient's hemodynamic requirements,

7. To provide improved blood-immersed bearings for rotary blood pumps, and,

8. To provide improved means of providing high flow washing of blood-immersed bearings and thereby prevent failure of the pump due to thrombus accumulation.

<u>THE FIGURES</u>

Figure 1 is a schematic drawing of the complete system indicating the position of the components.

Figure 2 is a drawing of an intraventricular axial flow pump in the heart.

Figure 3 is a longitudinal section of the blood pump showing the motor, bearing, and hydrodynamic blade positions.

Figure 4 is a longitudinal section of one pump configuration showing much pump thrombus at both the inflow and the outflow sides of the rotor.

Figure 5 is a longitudinal section of an improved configuration showing a small thrombus at the inflow side of the rotor.

Figure 6 is a longitudinal section of further improved configuration showing no thrombus at either end of the rotor.

Figure 7 is a longitudinal section of a generalized pump design having both inflow and outflow stators.

Figure 8 is a longitudinal section of the bearing details of a design as shown in Figure 5.

Figure 9 is a longitudinal section of the inflow side of a thrust and radial bearing design.

Figure 10 is a longitudinal section of the inflow bearing configuration of the preferred embodiment pump shown in Figure 3.

Figure 11 is a longitudinal section of a motor set using dual armatures and a single rotor.

Figure 12 is a schematic illustration of the laminations, windings, and rotor magnet of a three-phase motor.

Figure 13 is a detail of the windings of a motor similar to that shown in Figure 12 in which two sets of coils are utilized.

Figure 14 is a longitudinal section of a motor having two sets of coils like that shown in Figure 13.

Figure 15 is a schematic diagram of the electrical connections of the components of the system.

Figure 16 is a longitudinal section of a generally rectangular rib-shaped metal case containing electronics and batteries.

Figure 17 is a schematic illustration of the electronics and batteries for fit into the case illustrated in Figure 16.

Figures 18A & B are partially schematic longitudinal sections of two hermetically sealed electronics enclosures, metal bellows power conduits and wires within them, and the male and female sides of an implantable connector.

Figure 18C is an end view of the connector shown in Figure 18A.

Figure 19 is a longitudinal section of a standard metal bellows.

Figures 20 & 21 are longitudinal views of metal bellows electrical conduits having rigid tubular segments interposed between flexible metal diaphragms.

Figure 22 is a block diagram of the redundant electronics system.

SPECIFIC DESCRIPTION OF THE INVENTION

The life of the patient depends on the safety of the entire system which achieves extraordinary reliability by providing maximum backup capability. Complete electrical redundancy assures that the pump will continue to run despite failure of any electrical component. In the event of mechanical failure a valve is provided which prevents back flow so that the natural heart can effectively sustain the life of the patient until the system can be surgically replaced. Safety not only means avoidance of failure of the device to pump blood but also the system must remain free of infection, and be supported by the body without damage to any organs or tissues, under the stress of the continual flexing and motion during normal activity. The individual component design must be optimized, and also the integrated function of the system is a major aspect of the current invention.

THE OVERALL SYSTEM

Figure 1 illustrates the complete system. The intraventricular pump 2 is attached into the left ventricle 4 by sewing cuff 6. Blood enters it from the left ventricle and is pumped through the outflow graft 8 and through the valve 10 into the aorta 12. The pump is driven by an electric motor which has two separate sets of windings powered by two separate sets of motor wires. Both of these sets of wires pass through a metal bellows conduit 14, are separated at a "T" connector 16, and connect to one of two implanted electronics modules 18 and 20 contained within rib-shaped metal enclosures 22 and 24. These also contain rechargeable batteries with enough energy storage to power the device for about an hour when it is disconnected from any external power source. The rib shaped electronics and battery modules may be corrugated to permit them to be bent at surgery to conform to the individual curvature of the patient's rib cage.

They typically are fabricated from titanium alloy (Ti-6Al-4V) and may have a textured surface such as sintered titanium microspheres to promote tissue ingrowth and prevent infection.

Power for the system is provided by two externally worn rechargeable batteries 26 and 28, which may be high-capacity flexible polymer lithium-ion cells or other suitable types. These together typically provide 8-12 hours of power and are worn on a vest which is typically changed 2-3 times per day. The vest itself, which is not shown in the drawing for clarity, incorporates fasteners such as velcro or zippered pouches, which removably retain the batteries in proper position. Alternatively, the vest may locate the batteries generally at the waist rather than the shoulders. The vest includes fasteners to removably retain two power transmitter coils 30 and 32 in proper position adjacent to two internal receiver coils 34 and 36 implanted under the skin. Proper alignment of the internal and external coils, in addition to being generally maintained by the vest, may be further secured by means of mating permanent magnets (not shown) configured to both hold the external coil against the skin and to position it. Each external battery pack includes an electronics module 38 and 40 which include monitoring and alarm devices as well as the necessary electronics for battery charging and power transmission to the transmitter coils. The external cables 42 and 44 are typically sealed waterproof polymer cables which require no connectors. Power to charge the external batteries is delivered via the coils 30 and 32 as electromagnetic energy from a charging unit (not shown). The method of providing power across the intact skin via transmitter and receiver coils is well known in the literature and is referred to as TETS for Transcutaneous Energy Transmission System. In the present invention, redundant TETS systems are employed and the overall system is designed such that each external battery can provide power to both internal electronics modules via either one of the two sets of TETS coils. This permits one external coil at a time to be removed without loss of external power which protects the skin between the coils from damage due to unrelieved excessive pressure. Power from each of the internal TETS coils 34 and 36 is conducted to the two respective internal power modules 18 and 20 by wires within metal bellows conduits 46 and 48. Hermetically sealed internal

connectors 50, 52, 54, and 56 are provided to facilitate surgery and to permit replacement of any module of the system without replacement of the other components.

Another embodiment of the system utilizes direct electrical connection of external battery and control systems to the pump within the patient by means of a cable that penetrates the skin. This is referred to as percutaneous power transmission. The percutaneous embodiment has the advantage that no batteries or electronics other than the motor need be implanted within the patient. The redundant sets of motor wires are each connected to a separate external electronics control system and battery supply. In the event of failure of any component, the module containing it can easily be replaced without surgery. The wires are brought across the skin within a metal bellows conduit which is coated with a porous layer to promote tissue ingrowth and wound healing. This constitutes the percutaneous lead. Once outside the body, a "T" connector is used to separate the two sets of motor coils to two electronics systems. External waterproof connectors are provided to permit the batteries to be changed. While one battery is disconnected to change it, the other battery continues to power the pump. In the percutaneous embodiment, an internal connector is provided so that, in the event of a skin infection, a new percutaneous cable may be implanted at a different location, and the infected cable removed without changing the pump.

THE AXIAL FLOW PUMP

Figures 2 and 3 show the axial flow pump implanted at the left ventricular apex (Figure 2) and a close-up view of the device (Figure 3). The pump housing 58 is retained by sewing cuff 6 with the motor 60 and pump impeller 62 inside the heart. The pump rotor 64, which contains the magnet of the motor 66, spins within the motor bore, and is isolated from blood contact by a thin-walled titanium sleeve which lines the inside of the motor bore. Figure 3 best illustrates the preferred embodiment of the pump. Blood is entirely isolated from the motor cavity 68, by welded seams of the pump assembly, and likewise the rotor magnet is completely enclosed in a titanium shell with welded seams to exclude blood.

My previous U.S. Patent No. 4,994,078 disclosed the

principle of high-flow washing of the rotating and stationary components of the pump to prevent thrombus accumulation. Experience has demonstrated that additional principles not previously recognized or disclosed in the prior art may be specifically incorporated in axial flow blood pumps to enhance washing of these junctions and reduce thrombus within the pumps. The present invention provides an improved pump structure. Figures 4, 5, and 6 are scale drawings of actual pump flow path geometries tested in animals. The pump of Figure 4 utilized a rotor 70 having a blunt leading profile 72 and a steep hub outflow angle 74 of 24 degrees. After four months of use in a calf, this pump rotor seized due to thrombus 76 at the inflow side and thrombus 78 at the outflow side of the rotor. The inflow thrombus 76 was due a flow stagnation region around the inflow side bearing and the outflow thrombus 78 was due to a combination of factors. The pump blades included inflow stators 80, impeller blades 82, and outflow stators 84. Arrow 86 indicates the rotational component of the fluid flow leaving the impeller. Due to the steep angle of the impeller hub in this region of the pump, flow separation with a rotating eddy at 88 in the region of the outflow bearing occurred. Thus the junction of the rotating and stationary components of the pump at the outflow side was not in a region of high flow but was within a relatively stagnant portion of an eddy. The pump of Figure 5 completely eliminated thrombus at the outflow bearing as demonstrated in a five-month animal implant. No inflow stators are included but rather there are two inflow bearing support struts 90 and 92. The impeller 91 imparts about the same rotational flow to the blood indicated by arrow 94 as did the impeller of the pump of Figure 4. However, outflow stator blades 96 placed between the impeller and the outflow side bearing 98 redirect the rotational component of the flow to the axial direction as indicated by arrows 100 <u>before</u> the flow passes across the outflow bearing. Additionally, the outflow side of the rotor was designed with a flat taper angle 102 of only about 10 degrees to prevent flow separation. Thus there was neither flow separation nor a rotational eddy around the outflow bearing. It was well washed by high flow and therefore remained free of thrombus although it was exactly the same bearing design as used in the pump of Figure 4. The inflow side of the pump

rotor of Figure 5 was gradually tapered at 104 to avoid a flow stagnation area like at 72. However, a small thrombus 106 still formed at the inflow bearing junction because this junction was located in a flow stagnation region downstream from the bearing support struts 90, and 92.

Figure 6 illustrates a design which provides high flow across both the inflow and outflow bearings without stagnant eddies or fluid swirl around the bearings. This model pump is presently implanted in an animal which is not clinically anticoagulated and the device has functioned perfectly for more than three months at the time of submission of this patent application. We expect both the inflow and outflow junctions of the rotating and stationary parts of the pump to remain free of thrombus indefinitely. The inflow bearing is supported by a post extending axially from support struts 110 and 112. Thus the junction 114 at the inflow bearing is kept out of the flow stagnation region in the lee of the support struts. The rotor hub outflow side angle is even flatter -- only 6 degrees -- and the outer walls of the flow channel around the outflow stators 116 are also tapered at an angle 118 to further suppress flow separation. The outflow bearing is washed by a high-flow stream of axially flowing blood and is supported by a streamlined strut 120 projecting from the titanium wall of the pump.

The experimental findings of thrombus formation within the pump relate to the design of the flow channels and blades and not only to the washing of the junctions between the rotating and stationary components of the device. Although it is well known that turbulence, flow separation, and stagnation are detrimental to pump performance in general, the design of a permanent blood pump having blood-immersed bearings presents special problems related to the fact that the blood-clotting system, including thrombus formation and platelet properties, acts to form an adhesive system evolved to glue wounds together. This will also bind bearings if the surface area of the bearing is too great in relation to the forces applied to rotate them. Very small diameter bearings have the advantage of low surface area which limits the adhesive force of blood clotting. If the bearing diameter is minimized, the diameter of the magnets necessary to rotate the impeller must be considerably larger. If the magnets

are placed within the hub of a rotor carrying the impeller, there must be a taper on both ends of the hub if the blood-flow path is to wash directly across the bearings. If it does not there will be a crevice where clot will form. The design of the flow path around that taper is important. In the pump design of Figure 4, thrombus formed at both ends of the rotor in relation to the taper of the rotor hub. If the flow channel between the outflow side of the impeller and the outflow bearing increases in cross-sectional area too abruptly, the blood flow will separate and may form sufficiently stagnant eddies to clot. This appears to have occurred in the pump of Figure 4. The flow channel in this pump increases by more than 50% between the impeller and the outflow bearing over a short axial length. Positioning the stators between the impeller and the outflow bearings in the designs of Figures 5, 6, and 7 permits a gradual taper to the hub and prevents a rotating eddy around the bearing. In the pump of Figure 5 the cross-sectional area of the flow channel between the impeller and the outflow stators increases only 17% and in the pump of Figure 6 only the area increases by only 10%.

Figure 7 shows a generalized axial flow blood pump in which both inflow stators 122 and outflow stators 124 are provided. A rotor 126 with an impeller 128 is supported at both the inflow and outflow ends by support struts 130 and 132 which hold blood-immersed bearings at 134 and 136. Magnets (not shown) which rotate the rotor may be supported by the impeller blades or may be located within the hub of the rotor. The important feature of this design is that the blood stream washing across both the inflow and outflow bearings is substantially axial. Rotational fluid flow is confined to the region of the pump between the inflow and outflow stators.

THE BEARINGS

Figure 8 shows the inflow and outflow bearings utilized with pumps of the designs illustrated in Figures 4, 5, and 6. The rotor 64 supports two rotating ceramic bearing members 138 and 140. Each of these has a cylindrical shaft portion 142 and 144 which supports radial load. The inflow rotating bearing member 138 has a tapered surface 146 which mates with a similarly tapered surface of the stationary ceramic inflow bearing sleeve 148. Axial thrust load is born by contact at these tapered

surfaces. The tapered surface has two advantages. First, it is self-centering and contributes to radial load bearing capacity when thrust load is applied. Second, it provides a greater surface area to carry thrust load than bearings of the same diameter that are not tapered. This reduces the load per unit of surface area and reduces wear. The object is to obtain the highest load-bearing capacity at the smallest diameter to minimize surface rubbing speed, heat generation, and binding by blood adhesive properties. The inside bore of sleeve 148 is only slightly larger than the diameter of the shaft rotating within it. Typical radial clearance is a few ten-thousandths of an inch between the rotating bearing shaft pins 142 and 144 and the stationary ceramic sleeves 148 and 150 held by support struts 92 and 98. The diameter of the pins is typically .037" and thus in a pump typically operating at 10,000 RPM the bearing pin surface speed is only about 1.6 feet/second. The bearings are preferentially made of a very hard, wear-resistant ceramic having high thermal conductivity and high fracture toughness. The best material available to date appears to be a sintered silicon carbide material containing titanium diboride, although other materials can also be used. Using this material, in a five month animal study, wear measurements have indicated less than .000013" of wear on the thrust-bearing surfaces and less than .00005" radial wear on the shaft and bore surfaces. This extremely low wear is expected to permit the design to operate reliably for more than a decade.

Figure 9 illustrates another bearing design in which a tapered thrust-bearing surface 152 on the end of a rotating bearing pin 154 is combined with a radial load supporting cylindrical surface 156. The stationary bearing sleeve 158 is mounted into the support strut 92.

Figure 10 shows the preferred embodiment of the inflow bearing and support for optimal high blood flow washing and avoidance of thrombus. An extension post 160 extending from the inflow support strut 112 holds the stationary ceramic inflow bearing sleeve 162. A tapered thrust-bearing surface 164 is provided which mates with a similar surface on the rotating bearing member 166. The junction of the rotating and stationary parts at 168 is designed to minimize the crevice present. The

extension post 160, holds the bearing away from the support strut 112 so that the junction 168 is not in an area of flow stagnation downstream of the strut. The structure provides excellent axial blood flow across the bearing for both mechanical washing and optimal dissipation of heat generated by bearing friction.

THE MOTOR

Reliability of the system is enhanced by providing motor redundancy. Figure 11 shows a motor in which two separate armatures 170 and 172 are mounted about a single rotor 174 containing a motor magnet 176. Two separate sets of motor wires 178 and 180 power two sets of motor coils within each armature, and it is readily apparent that power need be applied to only one set of wires and coils in order for rotor 174 to be rotated. Thus, if any wire were to break while both sets of coils were operative, the motor would continue to run powered by the unaffected armature. If this general arrangement is utilized in a brushless DC motor the rotational positions of the coils in each armature must be set in proper position to assure the optimal motor torque. A motor having two separate sets of motor coils within one armature has the advantage that the proper alignment of both sets of coils is assured. Figure 12 illustrates the winding arrangement of a simple brushless DC motor. A stack of laminations 182 has three teeth 184, 186, and 188, and three slots 190, 192, and 194. The motor magnet is shown at 196. In this three-phase design, coils 198, 200, and 202 are wrapped around the teeth with the wires lying in the slots. Only one coil is wrapped around each tooth. Referring to the coil 202 wrapped around tooth 188, there are two ends of the wire 206, and 208. One of these is connected to ground and the other is intermittently connected to the power source with proper timing for commutation depending on the rotary position of the magnet. The ground wires from all three coils may be joined together to a common lead wire and thus four lead wires may be used to power the motor as represented by the four wires in the set 178 (in Figure 11). Figure 13 illustrates one tooth of a motor lamination set like that of Figure 12 having a different arrangement of windings to accomplish the motor redundancy. Two coils 212 and 214 are wrapped around tooth 210, rather than one coil as in the motor of Figure 12. Similarly, two coils are wrapped around each

of the other motor teeth. With proper connection and the use of two common leads (a separate common for each set of coils) two sets of motor wires are provided, each of which is sufficient to power the motor. Figure 14 illustrates a motor of this design, having a total of eight motor leads 216 and only one armature 218. Actually, two sets of four leads each 220 and 222 are provided. Depending on the number of motor phases and type of connections used, differing numbers of wires may be provided in each set. The essential principle is that two complete sets of motor coils and leads are provided.

INTERCONNECTION OF SYSTEM COMPONENTS

A highly redundant embodiment of the invention utilizing dual electronics and battery systems with a motor of the type illustrated in Figure 14 and a transcutaneous energy transmission system (TETS) is shown in Figure 15. The dotted line on the left encloses one set of components, and the second set is shown on the right. The external battery 224 is connected to the external electronics module 226 which is connected via cable 228 to the external TETS coil 230. This external subsystem is removable from the patient. The internal TETS coil 232 is connected via an implantable connector 234 to the internal electronics and battery module 236 contained in a rib-shaped enclosure. This module is connected via another implantable connector 238 to both the blood pump motor 240 via a four wire cable 242 and to the other implantable electronics and battery system 244 via a two-wire cable 246. Figure 16 shows the interconnection of the components within the rib shaped case 236. The electronics system 238 is connected by wires 240 to the battery 242, also shown in Figure 17. A metal cover 244 is welded to case 236 at 246 to effect a hermetic seal. The wires interconnecting the electronics to the other components outside the enclosure pass through a metal bellows conduit 248 which is welded to the case at 250. The other end of the metal bellows is hermetically bonded to a ceramic core of an implantable connector through which pass hermetically sealed wire feedthroughs.

THE CABLES

The implanted power cables are subject to frequent bending with motion of the patient. The use of metal bellows enclosures protects the wires from corrosive contact with body fluids. To

further assure long-term durability, multistranded coiled wires are used, as has proven successful with pacemaker wires. The metal bellows conduits are preferentially made of titanium alloy, as is all of the exposed metal surface of the implanted components. Figure 19 illustrates a typical standard metal bellows design in which multiple formed washer-like diaphragms are welded together to form a flexible tubular structure. In this type of design deep grooves 304 are present which become very narrow channels on the inside curvature of the bellows when it bends. These crevices are not well-exposed to vascularized tissue, and are subject to infection if bacteria or other organisms are present. Figure 20 shows a welded bellows conduit specifically configured to avoid deep narrow crevices even when the bellows bends. The conduit is composed of a multiplicity of short tube segments 306, 308, and 310 welded to pairs of diaphragms 312, 314, and 316 to form a continuous hermetically sealed tube. Only very shallow crevices 318 and 320 are present. The tubes may first be coated with titanium microspheres before welding to provide a porous surface for tissue ingrowth. Figure 21 shows a further improvement on this principle which eliminates the crevices entirely while maintaining good flexibility of the bellows conduit. Bellows subunits 322, 324, and 326 are each fabricated from a single piece of metal and have diaphragm portions at each end 328 and 330, and tube-like segments 332 between them. These subunits are welded at the outside periphery of the diaphragm portions 334 and 336 to form the hermetic seal. The subunits may be coated with sintered titanium microspheres in a fluidized bed at high temperature before being welded together. This provides an excellent textured outside surface for tissue ingrowth to further prevent infection. Alternatively, the segments may be first welded together and then coated with microspheres.

THE ELECTRONICS AND CONTROL SYSTEM

Figure 22 is a block diagram of the electronics system, which is composed of four subsystems. These include two external electronics and battery modules, which are each separately removable from the patient for recharging or service, and two implanted electronics and battery modules, which may be disconnected and replaced surgically. The system is designed for

high reliability utilizing redundancy and high reliability components. Two separate TETS systems are provided which permits the patient to remove one at a time while remaining on external power. An interconnection 246 between the two internal electronics system and associated switching is provided to connect the power received from either internal TETS coil to either internal electronics system where it may be used to recharge the internal batteries, directly power the blood pump, or both.

THE BATTERIES

Many types of batteries could be used and as future battery technology improves more options will become available. The presently preferred battery system uses polymer lithium-ion flat sheet cells which are stacked or folded in multiple layers. In the rib configuration, the individual battery layers are not bonded together which makes the stack flexible because as the rib-shaped case is bent to match the curvature of the individual patient, the layers slide against one another. Dry lubricant, such as teflon powder, may be placed between the layers to prevent them from sticking. The external battery also may also use dry lubricant between the layers to achieve a more flexible battery pack. Present polymer lithium-ion batteries developed by Bellcore have an energy density of 95-120 watt hours/kg. Using this type of batteries within two ribs of proper size to fit most patients, and based on the power requirements of the pumps tested to date, enough energy storage is provided in two "ribs" to operate the pump for about 2-3 hours under nominal conditions. The batteries may be recharged about 2000 times. Thus, if the patient disconnects from the external batteries for two hours each day, 2000 recharge cycles will provide about 2000/365 = 5.5 years before the batteries need to be replaced. To extend this time and provide a system which will function for a decade without reoperation, the electronics system includes control which alternately draws power from one battery and, the next time the system is operated for more than five minutes on battery power, uses the other battery. By this method, the patient may briefly remove the vest to change it without the system recognizing this as a period of significant internal battery discharge. The patient is instructed not to use battery power for

more than one hour each day. Thus the system (excluding short times for changing the battery vest) uses first one battery and then the other on alternate days. The system permits the internal batteries to function for 10-11 years without requiring surgical replacement, and all throughout this time period the patient has the benefit of both batteries being functional, rather than one battery being worn out during years 6-11 as if it had only been used during the first 6 years while the other was left unutilized.

THE PHYSIOLOGIC CONTROL SYSTEM

The internal systems are each provided with a microprocessor and sensors which detect the physiological condition of the patient and adjust the pump motor speed accordingly. The microprocessor systems also provide additional programmable motor speed control, such as the use of a variable speed cycle to open and close the valve in the outflow graft, to provide pulsatility, or to adjust the pump output for the proper levels for large vs. small patients. These functions may be programmed via a telemetry link from an accessory external computer such as a pocket sized PC (not shown) which may utilize the TETS coils for data transfer. Information may be transferred from the external computer to the external electronics system (located with the batteries) using a wireless method in the infrared or other electromagnetic spectrum. As an alternative to telemetry in the case of percutaneous systems the PC may be plugged into a connector and be interconnected with the external battery pack electronics system to act as the overall system command unit. The pocket controller may contain the system alarms, battery charge status indicators, liquid crystal display, and input buttons. The following is example of one control method.

> Patient A is a 130-lb. individual with a history of hypertension and myocardial infarction in NYHA class IV failure. His ejection fraction measured at catheterization prior to the device implant was 17%. In this patient, a programmed control regime is selected based on his body weight and poor myocardial function. The programmed regime sets pump speed for three levels of exercise (lying down, sitting, and walking) which are recognized by the system's

sensors. These speeds correspond to the appropriate flow at the differential pressure across the pump estimated for the patient. In this example, the flow lying down determined by the program regime will be 3-4 l/min., the flow sitting will be 4-5 l/min., and the flow walking will be 5-7 l/min. Based on measurements of the patient's aortic pressure, and an estimate of the mean ventricular pressure, the pump differential pressure estimate is determined and the motor speed necessary to achieve the desired flow range is calculated. This may be, for example, 7,200 RPM lying, 8,400 RPM sitting, and 10,500 RPM walking. Assume the patient is lying down. The motor speed will be 7,200 RPM. Flow will be generally in the 3-4 l/min. range but will not be determined precisely. When the patient stands up and begins to walk, the system sensors will recognize this and the motor speed will be automatically increased to 10,500 RPM. Flow will increase to the 5-7 l/min. range. Then, when the patient sits down, the sensors will recognize this and speed will automatically be reduced to 8,400 RPM, reducing flow to 4-5 l/min.

The information disclosed in the description of the present invention is intended to be representative of the principles that I have described. It will thus be seen that the objects of the invention set forth above and those made apparent from the preceding description are efficiently obtained and that certain changes may be made in the above articles and constructions without departing from the scope of the invention. It is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative but not in a limiting sense. It is also understood that the following claims are intended to cover all of the generic and specific features of the invention herein described and all statements of the scope of the invention which as a matter of language might be said to fall there between.

I Claim:

1. A high reliability blood pumping system comprising;

a. Blood pumping means actuated by a single rotor of an electric motor,

b. Electric motor armature means having dual sets of motor coils configured such that either set of coils provides sufficient electromagnetic force to rotate said rotor and actuate said blood pumping means,

c. Dual electronics power systems to supply electric energy to each motor coil with the proper commutation timing, each of said power systems respectively wired to one set of said dual sets of motor coils such that power to rotate said rotor may be provided by both power systems, and if any component of either set of coils, wiring, or power system fails or is temporarily turned off, the pump will continue to run driven by the remaining components.

2. The blood pumping system of claim 1 including, monitoring and control means operatively connected to both power systems such that if any component of either power system, motor coil, or wire fails, said control means assure that the blood pump is operated by the remaining components.

3. The blood pumping system of claim 1 in which said blood pumping means comprise an axial flow, mixed flow or centrifugal flow pump.

4. A high reliability cardiac assist system comprising,

a. an electrically powered blood pump,

b. an implanted electronics and battery system capable of powering and controlling said blood pump,

c. dual transcutaneous energy transmission systems, each having a set of coils comprised of an external transmitter coil and an internal receiver coil, each set capable of providing power to said implanted electronics and battery system such that one of said external transmitter coils can be removed without discontinuing power transmission by the other,

d. an external battery system, capable of providing power to said implanted electronics and battery system via either or both of said transcutaneous power transmission systems.

5. The high reliability cardiac assist system of claim 4 in which said blood pumping means comprise an axial flow, mixed flow or

centrifugal flow pump.

6. A high reliability hydrodynamic blood pump cardiac support system utilizing residual function of the natural heart as an emergency backup comprising;

a. a hydrodynamic blood pump connected between the left ventricle and aorta by inflow and outflow conduit means or between the right ventricle and pulmonary artery by inflow and outflow conduit means,

b. a valve in said outflow conduit means preventing back-flow into the ventricle in the event said pump stops,

c. pump control system means adapted to vary the pump flow so as to cause said valve to close and open periodically at a frequency sufficient to prevent thrombosis due to stagnation of blood around the valve.

7. The high reliability hydrodynamic blood pump cardiac support system of claim 6 in which said blood pump is implanted within the natural heart.

8. A blood-immersed bearing adapted to support one end of a rotor on which is mounted the impeller of a hydrodynamic blood pump, comprising;

a. a rotating bearing component having both cylindrical and conical load-bearing surfaces formed of a corrosion- and wear-resistant material,

b. a stationary bearing component having surfaces adapted to bear both radial and axial thrust load in mating contact with said cylindrical and conical surfaces of said stationary bearing component, also formed of a corrosion- and wear- resistant material, and,

c. said bearing components forming a circular crevice of minimal depth at the exposed junction between them the circumference of which crevice is not more than 25% of the circumference at the tip diameter of the impeller of said pump.

9. An electrically powered blood pump, comprising;

a. Electric motor means including stationary windings and permanent magnet rotor means,

b. Two blood-immersed bearings supporting both ends of said rotor means for rotation around its axis, one of said bearings located on the inflow side of the rotor and the other on the outflow side,

c. A generally tubular blood filled conduit extending through said motor windings and having an annular blood channel formed between said motor windings and said permanent magnet rotor means,

d. Axial flow impeller means mounted upon said motor rotor within said annular channel,

e. An elongated, generally conical tapered hub of said rotor means maintained within said conduit means and extending from the vicinity of the impeller to the bearing means on the outflow side of the pump, having an angle of taper not greater than 10 degrees measured between the rotational axis and the conical surface of the hub,

f. Stationary outflow stator blade means affixed to the inside of said tubular conduit means and extending inward therefrom, such that said stator means redirect the rotational component of the blood flow produced by said impeller to a generally axial direction before said flow passes across the outflow side bearing.

10. An axial flow blood pump rotor and blade structure adapted to provide optimal washing of blood-immersed bearings which support said rotor, comprising;

a. a housing having a generally tubular channel through which blood flows and within which a pump rotor is mounted for rotation,

b. an elongated rotor having an inflow end across which blood flows before reaching a pump impeller mounted on said rotor and an outflow end across which blood flows after passing said impeller,

c. bearing support means upstream of said rotor, supporting blood-immersed inflow bearing means,

d. one or more pump impeller blades mounted upon said rotor,

e. an elongated rotor hub extending between the outflow side of said impeller and the outflow end of said rotor,

f. bearing support means downstream of the end of said rotor supporting blood-immersed outflow bearing means,

g. one or more stationary outflow stator blades fixed to the inside wall of said housing through which the blood is pumped and axially located between said impeller and said outflow

bearing means and so configured as to redirect the rotational component of the fluid flow stream exiting the impeller to a substantially axial direction before said flow stream crosses said outflow bearing means,

h. a pump flow channel within said housing comprised of the spaces between said housing, said rotor, said bearing support means and said bearings, configured such that, under the operating conditions of the pump, turbulence, flow separation, and flow stagnation sufficient to cause failure of the pump due to thrombus formation is prevented.

11. The axial flow blood pump of claim 10 in which the cross-sectional area of said pump flow channel at the upstream edge of said outflow stator blade is no more than 20% greater than the cross sectional area at the downstream edge of said impeller blade.

12. The axial flow blood pump of claim 10 in which said rotor is tapered at each end to a diameter 1/3 or less than the maximum rotor diameter.

13. The axial flow blood pump of claim 10 in which said bearing support means upstream of said rotor includes a stationary blood-immersed bearing sleeve at the end of an axially extending generally cylindrical post which is no more than 20% larger in diameter than the outside diameter of said bearing sleeve and the axial length of said post is at least twice its diameter.

14. An electronics and battery system implantable enclosure comprising;

a. a corrosion-resistant hollow metal case formed to occupy the space of a removed rib and to contain electronics and battery components,

b. a cover welded to said case so as to enclose electronics and battery components therewithin and provide electrical connection thereto via hermetically sealed feedthroughs.

15. The enclosure of claim 14 in which said case is provided with bellows like convolutions and together with the electronics and batteries within it, is sufficiently malleable so that it can be bent to match the general curvature of the removed rib in place of which it is to be implanted.

16. The enclosure of claim 14 having a porous metal surface coating of the same metal of which the case is composed.

17. An implantable connector and electric wire enclosure system for separably electrically interconnecting two hermetically sealed implantable metal enclosures comprising;

a. a ceramic electrical connector having two separable parts with male and female pins and receptacles hermetically sealed by ceramic to metal bonds,

b. a metal casing hermetically sealed around each of said separable connector core parts by a metal to ceramic bond,

c. two metal bellows through which electric wires pass connected to the respective male and female pins of said connector, each bellows welded to said metal casing around said connector core on one end of said bellows and to said implantable enclosure on the other end,

d. o-ring or other sealing means for removable sealing the two respective separable parts of the connector to each other,

e. retention means for holding the two separable parts of said connector together.

18. A flexible hermetically sealed conduit for the isolation and protection of electric wires interconnecting two components of an implanted prosthetic device, comprising an elongated metal bellows through which said electric wires pass fixed at each end to one of the respective two components.

19. The conduit of claim 18 in which a plurality of tubular segments are interspersed with a plurality of welded metal diaphragms.

20. The conduit of claim 18 comprised of a plurality of welded subunits, each subunit formed or machined from a single piece of metal and having a diaphragm at each end and a central cylindrical portion between said diaphragms.

21. A hollow flexible tubular percutaneous lead, adapted to penetrate the skin, heal to the skin, and provide a route of access into the body through which wires, tubes, fluids, or other structures or substances may be passed, comprising an elongated metal bellows having on its outside surface a porous layer of the same metal of which it is composed.

22. The percutaneous lead of claim 21 in which a plurality of tubular subunits having a porous metal surface layer are welded metal diaphragms in a repeating structure having metal washer-shaped diaphragms welded to one another and welded to said

tubular subunits.

23. The conduit of claim 21 comprised of a plurality of welded subunits, each subunit formed or machined from a single piece of metal and having a diaphragm at each end and a central cylindrical portion between said diaphragms.

24. A wearable electric power storage system comprising;

a. a fabric or polymer vest,

b. two flexible generally u-shaped battery packs composed of a plurality of individual interconnected cells configured to be worn over each shoulder,

c. means to removable retain said batteries in position over the shoulders of said vest, and,

d. power cable means to draw power from and to recharge said batteries.

25. A battery and battery use management system to provide alternate or sequential use of two or more implanted batteries which intermittently power an implanted blood pump otherwise powered by an external energy source comprising;

a. two or more implanted batteries each capable of independently powering said pump,

b. monitoring and sensor means to detect the state of each battery including its charge and whether it is charging or being discharged,

c. switching means to selectively utilize one battery at a time to power said pump,

d. timing means to detect when use of each battery to power said pump is switched on or off,

e. control means including computer hardware and software to operate said switching means and thereby to sequentially utilize a different battery from the one last utilized each time the system is switched from external to internal power and maintained on internal power for more than a brief (and programmable) period of time.

FIG 1

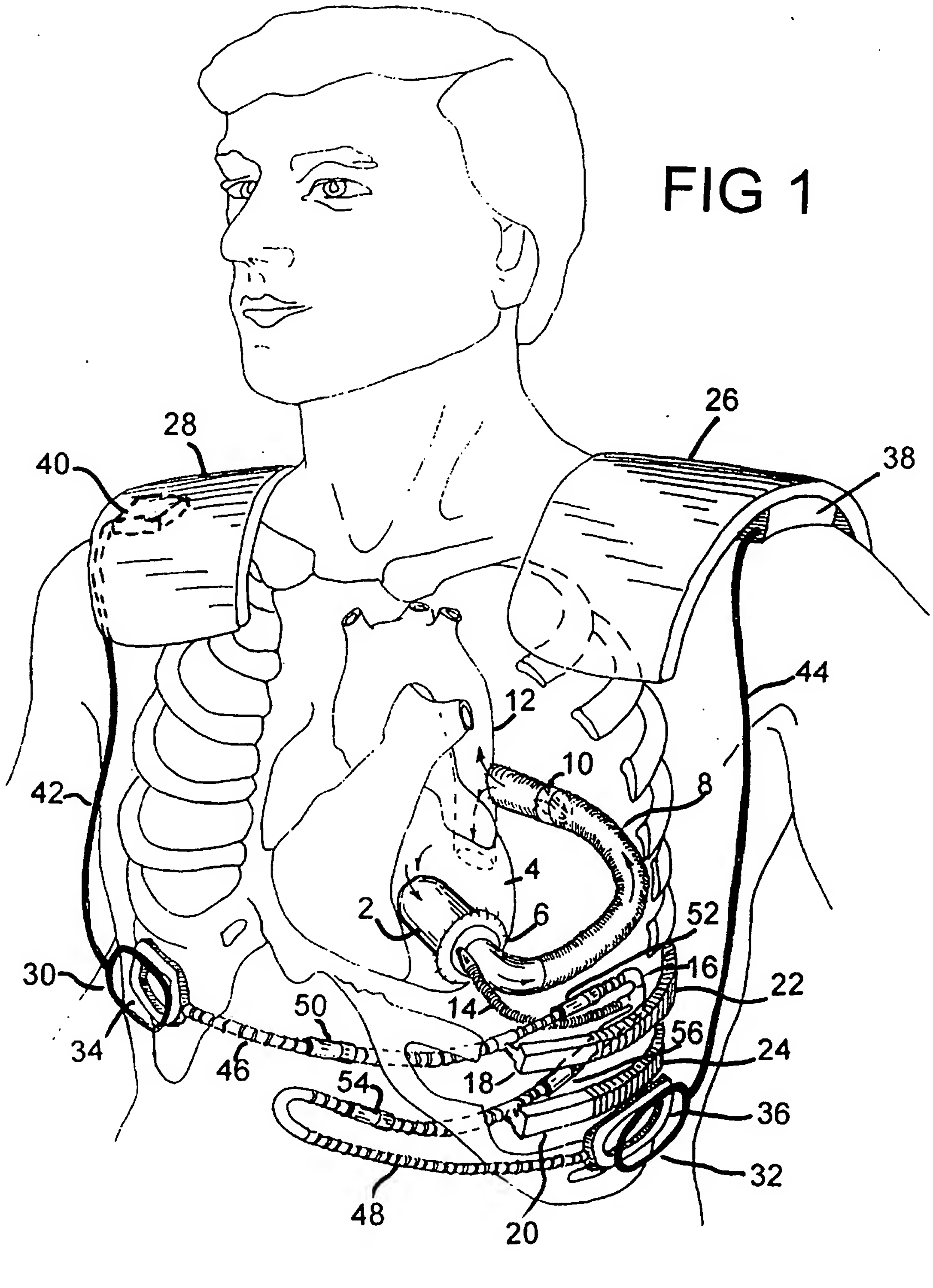

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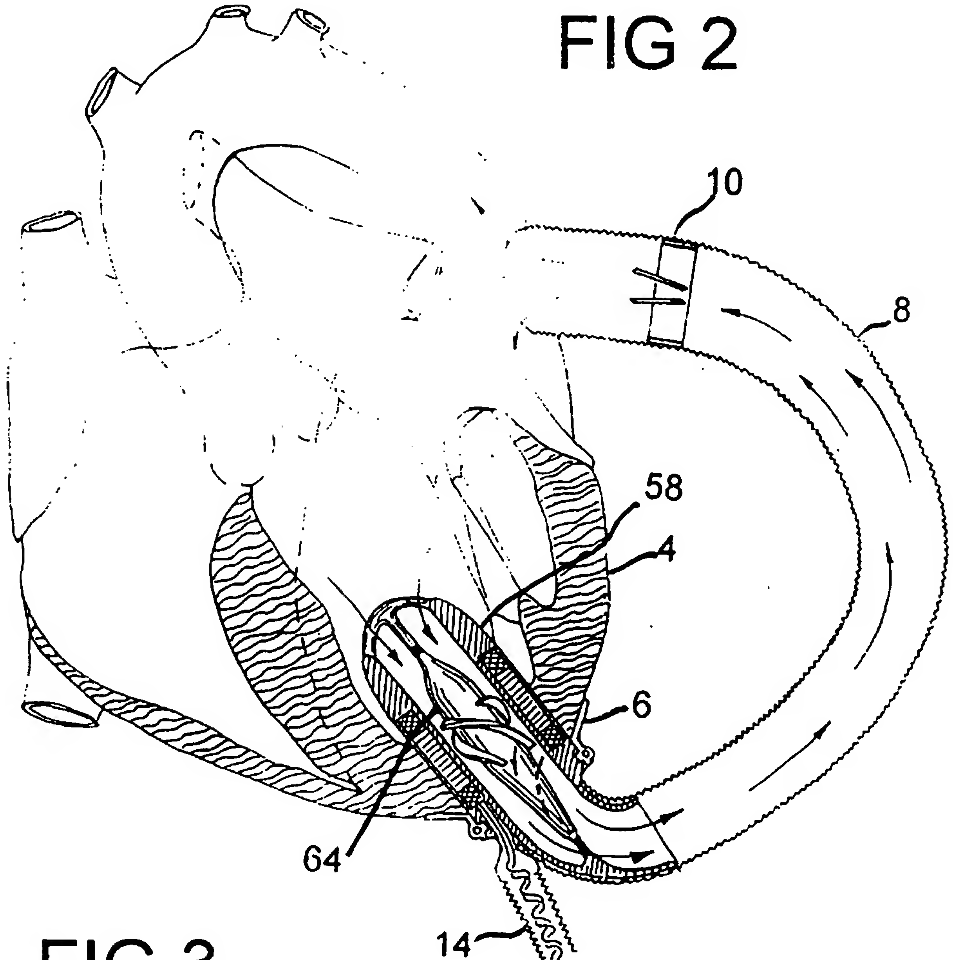
FIG 2



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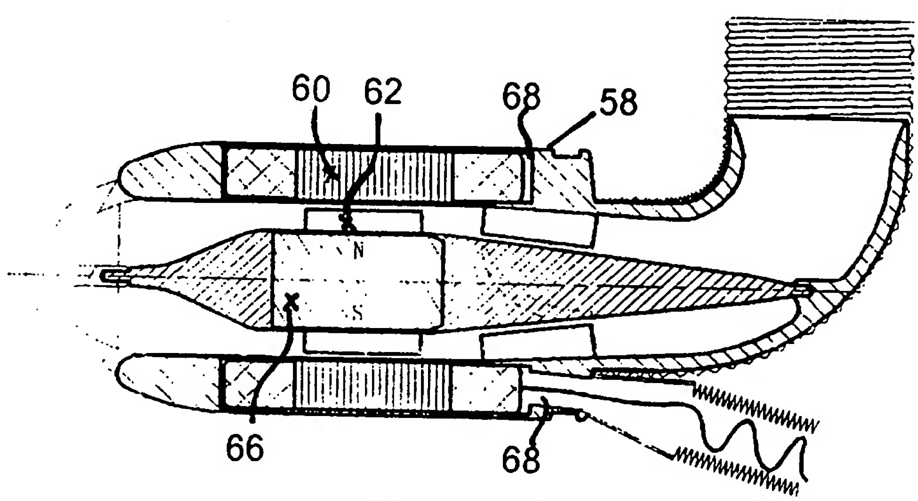

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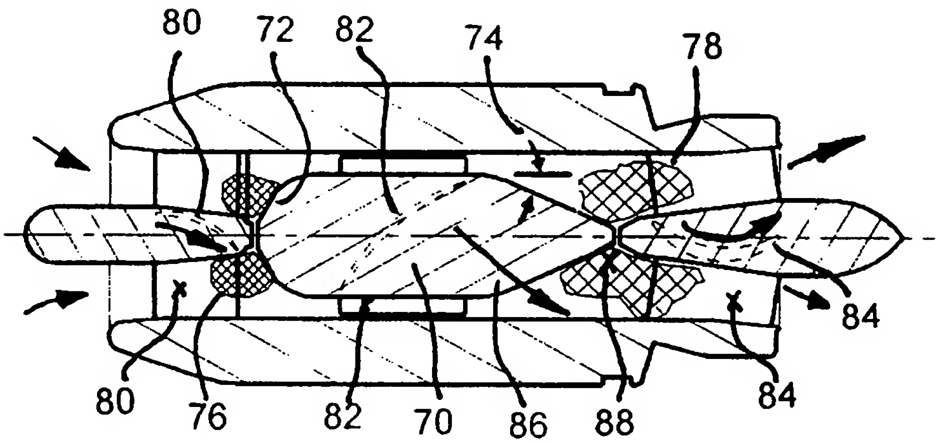


FIG 5

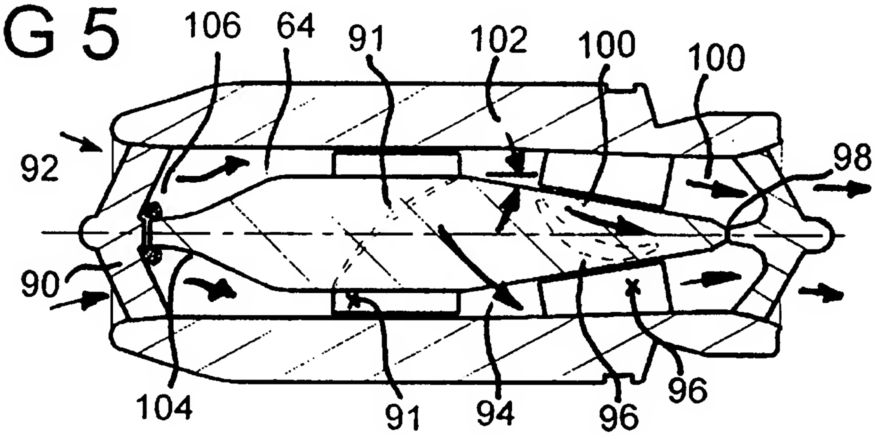


FIG 6

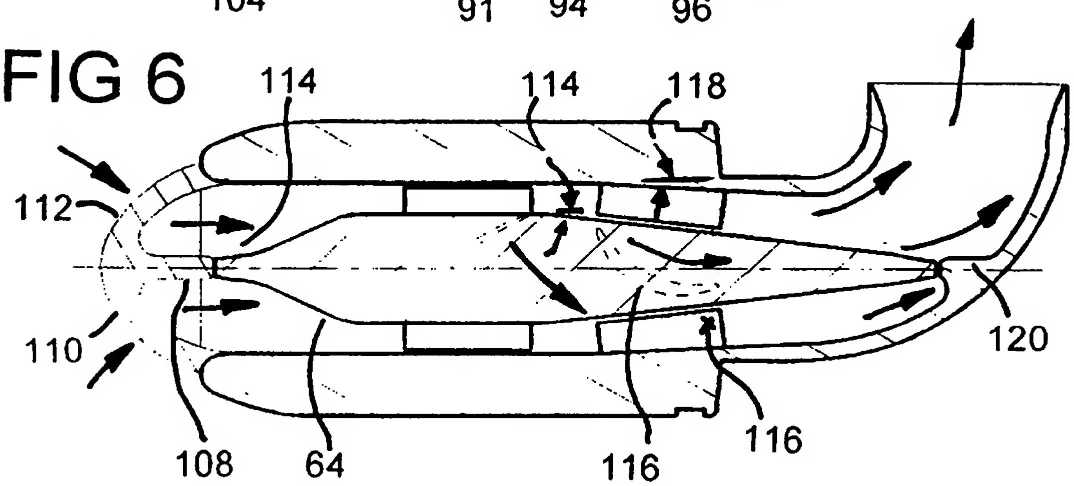


FIG 8

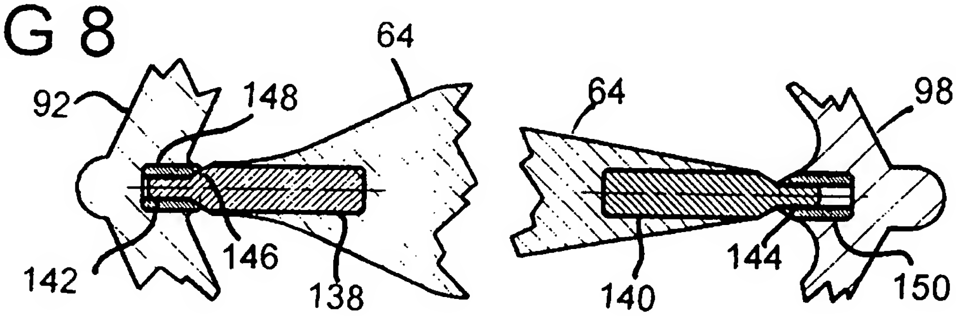


FIG 9

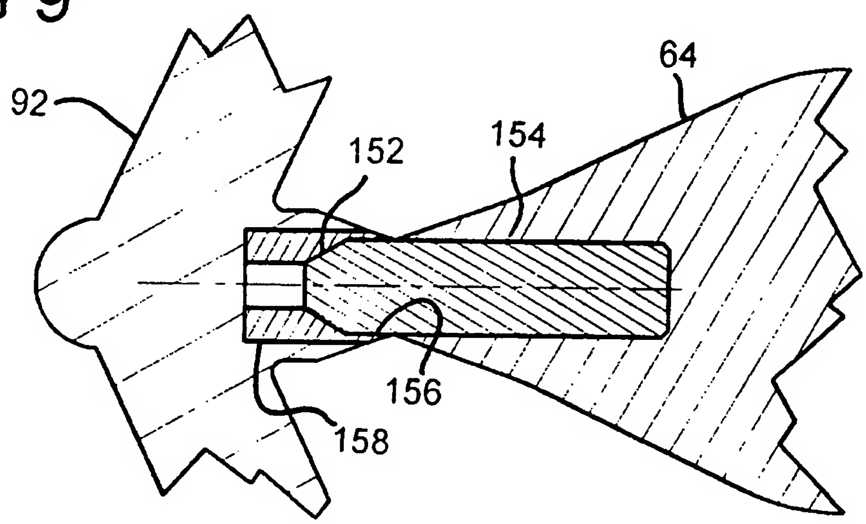
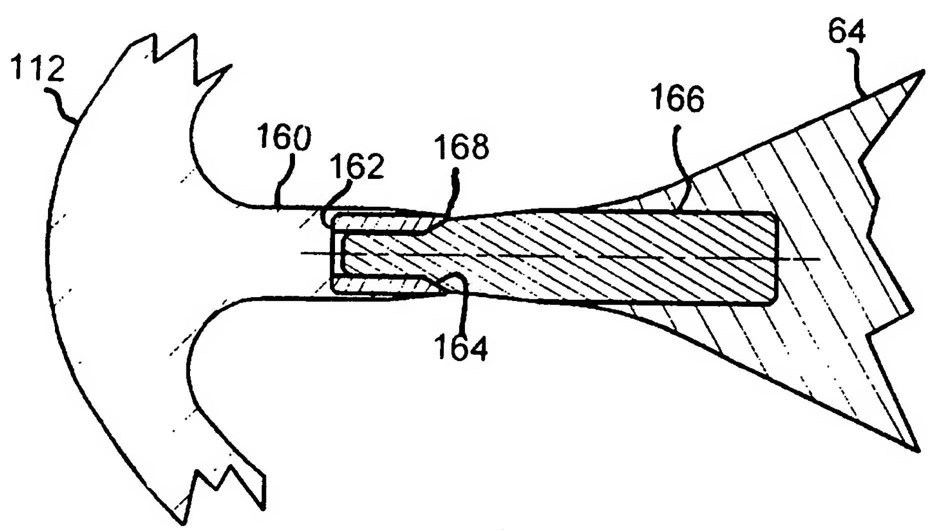


FIG 10



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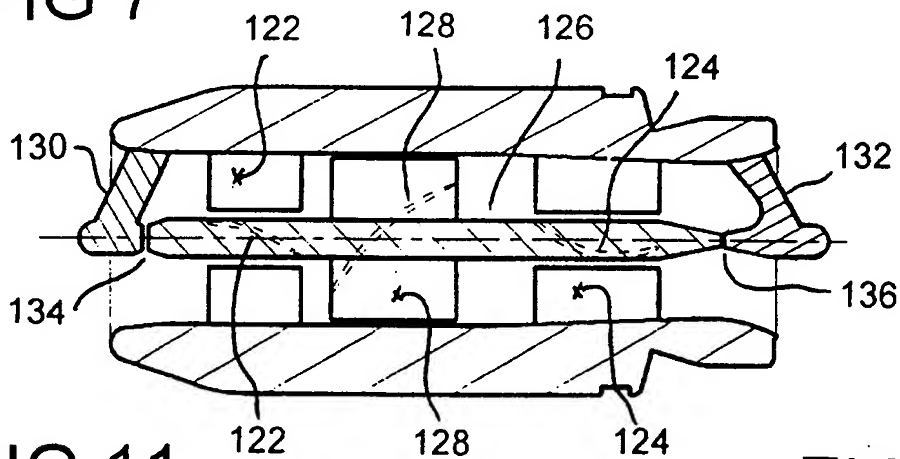


FIG 11

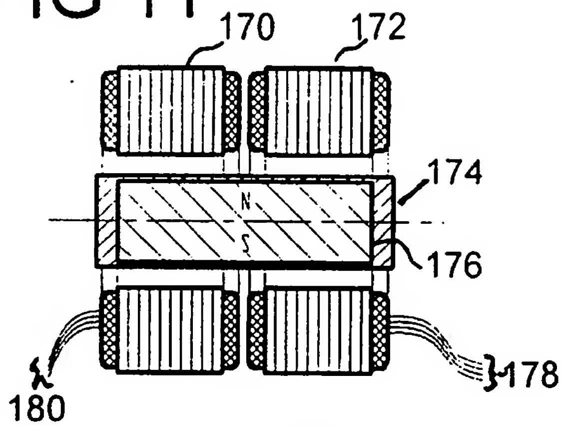
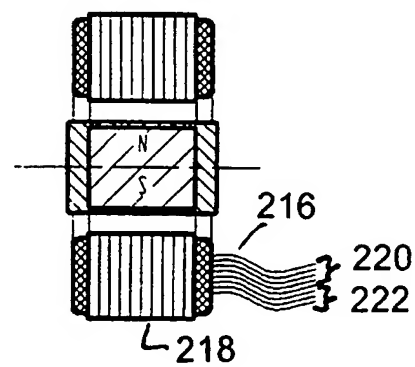


FIG 14



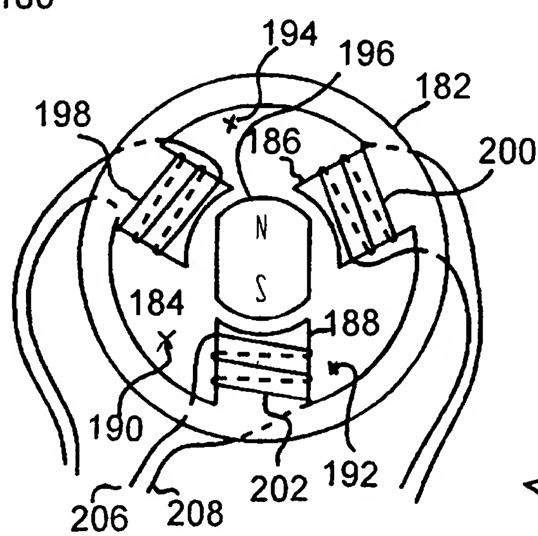


FIG 12

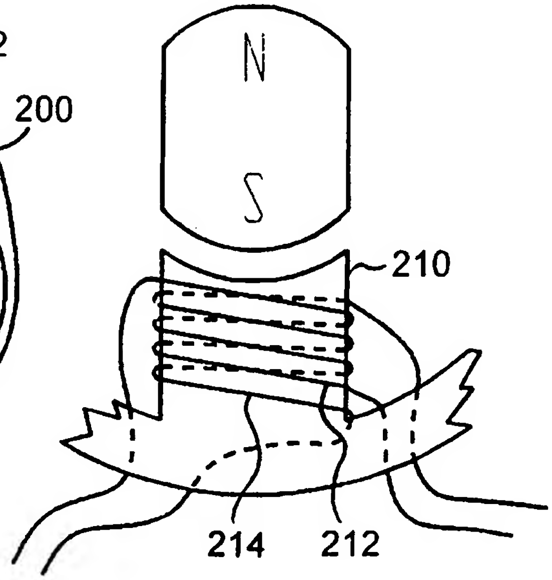


FIG 13

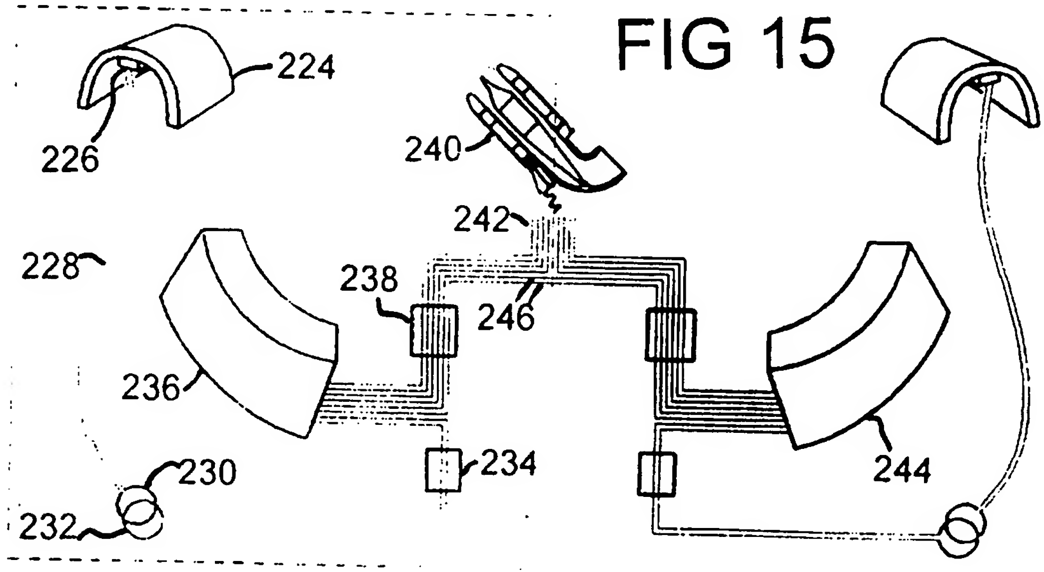

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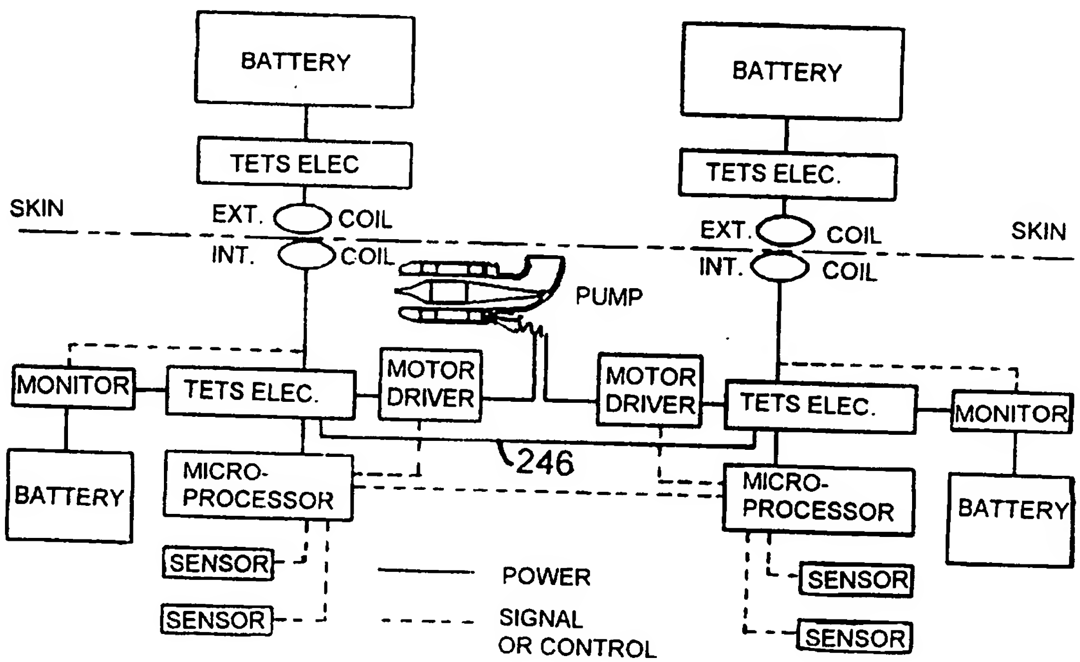
FIG 15

FIG 22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BATTERY
SENSOR
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POWER
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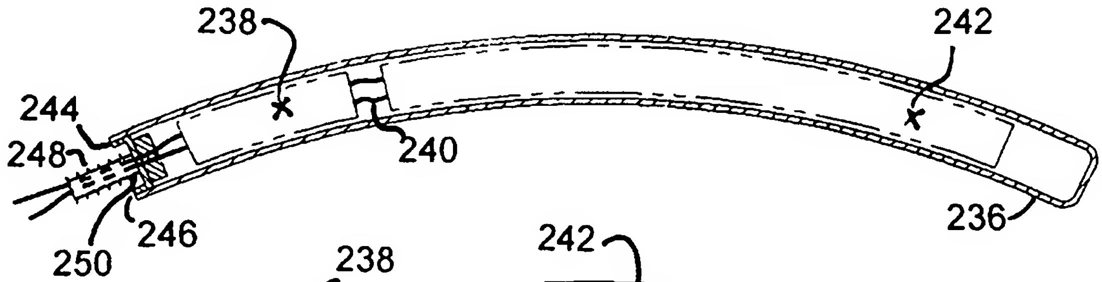
SENSOR
SENSOR

FIG 16



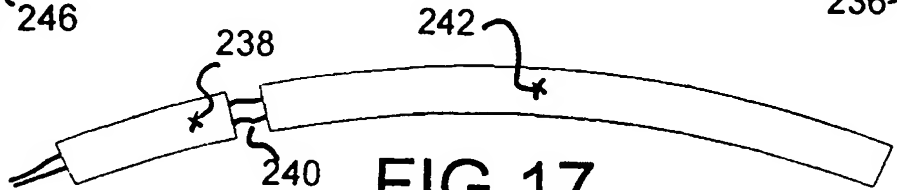


FIG 17

FIG 18A

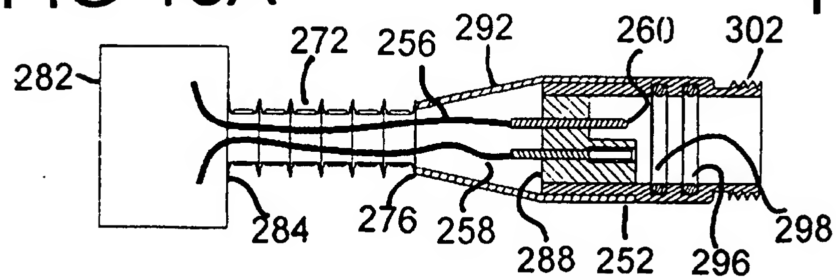


FIG 18C

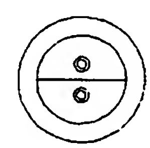


FIG 18B

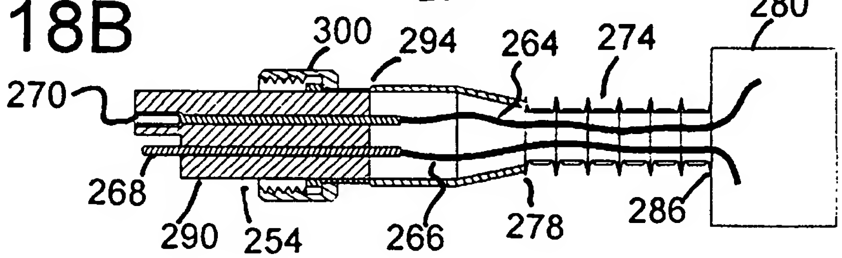


FIG 19

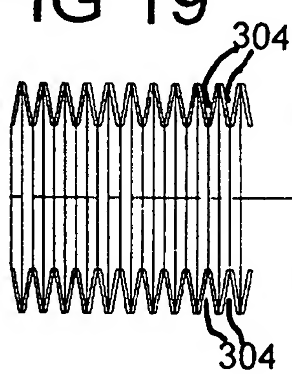


FIG 20

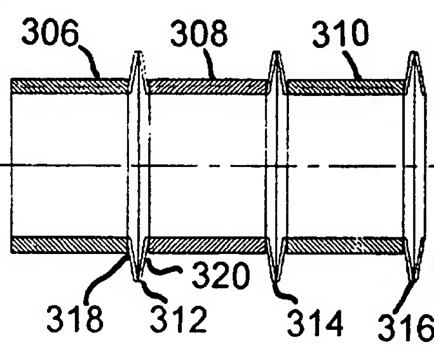
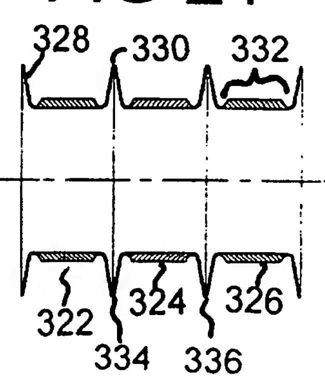


FIG 21



INTERNATIONAL SEARCH REPORT

International application No. PCT/US95/10760

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61F 1/24
US CL :600/016
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/903; 600/16; 607/33

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 5,370,509 (GOLDING) 06 December 1994, see entire document.	1-3
Y	US, A, 5,317,220 (GODKIN) 31 May 1994, see entire document.	1-3
Y	US, A, 4,134,408 (BROWNLEE) 16 January 1979, see entire document.	4, 5
X	US, A, 4,704,121 (MOISE) 03 November 1987, see entire document.	6, 7
A	US, A, 4,763,660 (KROLL) 16 August 1988, see Abstract.	24

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be part of particular relevance

"E" earlier document published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
16 JANUARY 1996	06 FEB 1996
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer for SCOTT GETZOW
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